Please Deliver Immediately to Examiner John D. Pak of Group Art Unit 1616

IN THE UNITED STATES PATENT OFFICE

Application Serial No. 10/020,882

Our Ref: PT-1949001
CUSTOMER NO. 23607

Filing Date: December 19, 2001

Applicant: Dialysis Solutions Inc.

Agent: Neil H. Hughes, P.Eng.
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Title: STERILE LOW BICARBONATE DIALYSIS CONCENTRATE SOLUTIONS

Examiner: John D. Pak

Group Art Unit: 1616

No. of Pages of Response including this sheet: 12

DELIVERED TO FACSIMILE NO. 1-571-273-8300

Dear Sir:

Amendment After Notice of Allowance
Pursuant to 37 CFR 1.312(a)

CERTIFICATION OF FACSIMILE TRANSMISSION

I hereby certify that this paper is being facsimile transmitted to the United States Patent Office Facsimile No. 1-571-273-8300 on the date shown below, including:

1. Amendment after Notice of Allowance pursuant to 37 CFR 1.312(a);
2. Periodic Table from the Merck Index; and
3. Mass Balance Work Sheet.

Signature: _____ Date: October 15, 2007

Neil H. Hughes, P.Eng.
Registration No. 33,636
Agent for Applicant

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OCT 15 2007

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Application Serial No. 10/020,882

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Applicant: Dialysis Solutions Inc.

Agent: Neil H. Hughes, P.Eng.
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Title: STERILE LOW BICARBONATE DIALYSIS CONCENTRATE SOLUTIONS

Inventors: Sheldon Tobe

Filing Date: December 19, 2001

Examiner: John D. Pak

Group Art Unit: 1616

AMENDMENT AFTER NOTICE OF ALLOWANCE
PURSUANT TO 37 CFR 1.312(a)

October 15, 2007

VIA FACSIMILE 1- 571-273-8300

The Commissioner of Patents
UNITED STATES PATENT AND TRADEMARK OFFICE
Customer Service Window, Mail Stop ISSUE FEE
Randolph Building
401 Dulany Street
Alexandria, VA 22314 U.S.A.

Dear Sir:

Applicant respectfully requests that the following submissions be entered as an Amendment after Notice of Allowance under 37 CFR 1.312. This amendment was not required by the Examiner prior to the issuance of a Notice of Allowance.

Prior to payment of the issue fee, Applicants Agent in reviewing the disclosure identified an inadvertent error with regard to the numerical value of MgCl2 in the concentrate. This inadvertent error was first identified and corrected in the prosecution of corresponding European Application EP 1347795. The corresponding Canadian Patent 2,365,789 may also be corrected as well. Therefore, Applicant respectfully requests that this amendment be accepted since it has no impact on the claim set as allowed whatsoever. If there is any requirement for fees for the following amendments, please obtain such fees from Deposit Account 08-3255 and advise Applicant's Agent.

In the disclosure, please amend the following paragraph's which included the same repeated inadvertent error:

AMENDMENTS TO THE DISCLOSURE: (as filed by Applicant)

Please replace the paragraph found on page 7, lines 31-32 through to page 8, lines 1-2 with the following paragraph:

In a first embodiment, the present invention provides a sterile calcium-free low bicarbonate concentrate comprising: sodium choloride (NaCl) 90.72 ± 9.0 g/l, sodium bicarbonate (NaHCO3) 28.35 ± 2.8 g/l, and magnesium chloride (MgCl2) ~~2.05 ± 0.2 g/l~~ **0.96 ± 0.09 g/l**.

Please replace the paragraph found on page 9, lines 13-23 with the following paragraph:

The present inventors have developed a sterile calcium-free low bicarbonate concentrate containing magnesium, sodium, chloride and a low concentration of bicarbonate that can be used in a number of novel applications. In a first embodiment, the present invention provides a sterile calcium-free low bicarbonate concentrate comprising sodium chloride (NaCl) 90.72 ± 9.0 g/l, magnesium chloride (MgCl2) ~~2.05 ± 0.2 g/l~~ **0.96 ± 0.09 g/l** and sodium bicarbonate (NaHCO3) 28.35 ± 2.8 g/l. The concentrate may also contain potassium, dextrose and/or ketones such as b hydroxy-butyrate. The concentrate can be stored at room temperature, preferably for an extended period of time. In one embodiment, the concentrate can be stored for at least up to 48 months.

Please replace the paragraph found on page 11, lines 19-27 with the following paragraph:

In a further aspect, the present invention provides a method for providing continuous renal replacement therapy to a patient comprising administering a sterile low bicarbonate dialysis solution comprising Na 140 ± 14 mmol/l, Mg 0.75 ± 0.07 mmol/l, Cl 116.5 ± 11 mmol/l, and HCO3 25.0 ± 2.5 mmol/l to a patient in need thereof. The present invention also provides a use of concentrate according to the first embodiment comprising sodium chloride (NaCl) 90.72 ± 9.0 g/l, magnesium chloride (MgCl2) ~~2.05 ± 0.2 g/l~~ **0.96 ± 0.09 g/l**, and sodium bicarbonate (NaHCO3) 28.35 ± 2.8 g/l for preparing a dialysis solution for use in continuous renal replacement therapy.

Please replace the paragraph found on page 11, lines 28-32, through to page 12, lines 1-7 with the following paragraph:

In a further aspect, the present invention provides a method for providing continuous renal replacement therapy to a patient comprising administering a sterile low bicarbonate dialysis solution comprising Na 140 ± 14 mmol/l, Mg 0.75 ± 0.07 mmol/l, Cl 116.5 ± 11 mmol/l, and HCO3 25.0 ± 2.5 mmol/l to a patient in need thereof. The present invention also provides a use of concentrate according to the first embodiment comprising sodium chloride (NaCl) 90.72 ± 9.0 g/l, magnesium chloride (MgCl2) ~~2.05 ± 0.2 g/l~~ **0.96 ± 0.09 g/l**, and sodium bicarbonate (NaHCO3) 28.35 ± 2.8 g/l for preparing a dialysis solution for use in continuous renal replacement therapy.

Please replace the paragraph found on page 11, lines 29-32, through to page 12, lines 1-7 with the following paragraph:

The dialysis solution of the invention is preferably used to treat acute renal failure in critically ill patients. In contrast to prior art dialysis methods, the treatment typically does not involve incorporating calcium into the blood using the dialysis procedure. Therefore, the invention also contemplates a method for treating acute renal failure in a critically ill patient comprising dialyzing blood from the patient without introducing calcium into the blood removed from the patient during dialysis, and using a sterile dialysis solution prepared by mixing a sterile diluent with a sterile low bicarbonate concentrate according to the first embodiment comprising NaCl 90.72 ± 9.0 g/l, MgCl2 ~~2.05 ± 0.2 g/l~~ **0.96 ± 0.09 g/l**, and NaHCO3 28.35 ± 2.8 g/l. The dialysis solution may additional contain potassium, up to 4 mmol/litre, glucose up to 5 mmol/litre and/or b hydroxyl-butyrate or other ketones, up to 5 mmol/litre.

Please replace the paragraph found on page 13, lines 1-6 with the following paragraph:

The present invention includes kits for preparing dialysis solutions. In one embodiment, the present invention provides a kit for preparing a dialysis solution comprising (a) one 240 ml unit of a concentrate comprising sodium chloride (NaCl) 90.72 ± 9.0 g/l, magnesium chloride (MgCl2) ~~2.05 ± 0.2 g/l~~ **0.96 ± 0.09 g/l**, and sodium bicarbonate (NaHCO3) 28.35 ± 2.8 g/l and optionally (b) three litres of sterile water or another suitable diluent.

Please replace the paragraph on page 14, lines 26-32 through to page 15, lines 1-4 with the following paragraph: